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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,323	03/20/2000	STEFAN SANNER	258.00040101	2155

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

9

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,323

Applicant(s)

SANNER, STEFAN

Examiner

P. Kathryn Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-8, 10-21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8 and 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 13 May 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The cancellation of claims 4-6, 9 and the addition of claims 13-21 is acknowledged and has been entered into the record. Additionally, any objection/rejection not repeated herein has been withdrawn.

Election/Restrictions

2. Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- I. Claims 1-20, drawn to a device for taking and examining sample in a housing, classified in class 422, subclass 58.
- II. Claim 21, drawn to a method for taking and examining samples, classified in class 436, subclass 174.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus or by hand, see for example the process for specimen handling for analysis of nucleic acids in Stapleton (USP 5,436,129).

4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, penultimate line, the conditional phrase "can be" or "can additionally be" are not positive recitations, therefore, renders the claim indefinite. Same deficiency was found in claim 13.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 8, 11-12, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (USP 4,770,853).

Bernstein discloses a device for self-contained solid phase immunodiffusion assay. The

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device comprising a housing 13 in which a cartridge 15, testing means 18 and sample taking means 2 are positioned. Additionally, the cartridge and testing means are displaceable within the housing such that the testing means is brought into contact with the sample mixture for analyzing this mixture. The sample-taking means comprising threads 18-19, 21 couples to corresponding internal thread, or nodule 4, of the housing (Figs. 1-6). Bernstein teaches the use of membranes 7 to contain the reagents.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (USP 4,770,853) in view of Berger (USP 4,269,237).

Bernstein as previously discussed above, does teach a rupturable membrane for controlling the flow of the material through the cartridge. However, Bernstein does not recite the specific use of a ball for closing the opening of a cartridge. However, the use of ball valves is

considered conventional in the dispensing art, see Berger. Berger device for draining or collecting sump oil from a container, wherein the container has a drain plug closed by a ball valve or rupturable membrane (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have substituted the rupturable membrane means of Bernstein, with the ball valve, as taught by Berger. Ball valves are known within the art to provide reliable sealing which can be reused repeatedly.

Response to Arguments

13. Applicant's arguments filed May 13, 2002 have been fully considered but they are not persuasive. In response to the previous rejection of claims 1-3, 8, 11-12 under 35 U.S.C. 102(b) as being anticipated by Bernstein (USP 4,770,853), Applicant argues that the testing means and the cartridge of Bernstein are not "displaceable" within the housing as claimed. Examiner contends that process limitation describing the movement of the testing means and cartridge as being "displaceable" has not received patentable weight, since process limitations do not receive patentable weight in a claim drawn to an apparatus. Additionally, Examiner believes the testing means and cartridge of Bernstein are in fact "displaceable" since Bernstein disclose the placement and positioning of the vessels (e.g. cartridges) in the cylindrical tube (e.g. housing), see column 6, lines 8-10. Moreover, Bernstein teaches the placement of rabbit immunoglobulin on the control membrane (e.g. testing means) before placement in the housing, see column 6, lines 14-18.

Allowable Subject Matter

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14. Claims 13-18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: see previous Office Action.

Conclusion

16. No claims allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
July 11, 2002

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